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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

KFX MEDICAL CORPORATION, a Delaware corporation, Plaintiff and Counterdefendant, v. ARTHREX, INCORPORATED, a Delaware corporation, Defendant and Counterclaimant.	Case no. 11cv1698 DMS (BLM) **PLAINTIFF'S MEMORANDUM OF CONTENTIONS OF FACT AND LAW** REDACTED - PUBLIC VERSION Trial Date: August 19, 2013 Time: 9:00 A.M. Courtroom 13A Honorable Dana M. Sabraw

CONTAINS CONFIDENTIAL INFORMATION – FILED UNDER SEAL

TABLE OF CONTENTS

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF CONTENTS
(*cont'd*)

Page No.

TABLE OF AUTHORITIES

Page No(s).

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

TABLE OF AUTHORITIES
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OTHER AUTHORITIES

Pursuant to Local Rules 16.1(f)(2) and 16.1(f)(3)(e), KFx Medical Corporation ("KFx") provides the following Memorandum of Contentions of Fact and Law. As required by the Local Rule, this memorandum provides a concise statement of the material facts and the points of law on which KFx intends to rely. It does not purport to be exhaustive or to address every item of evidence that KFx may offer at trial.

I. BACKGROUND

KFx owns U.S. Patent Nos. 7,585,311 ("the '311 patent"), 8,100,942 ("the '942 patent"), and 8,109,969 ("the '969 patent") (collectively, "the KFx patents"). The KFx patents concern a method of attaching soft tissue, such as a tendon, to bone. The patented methods can be used in a number of applications, but primarily have been used for arthroscopically repairing a torn rotator cuff.

Prior to advancements in arthroscopic surgeries, rotator cuff repairs were performed as "open" surgeries, requiring large, invasive incisions. Although arthroscopic procedures allowed surgeons to perform minimally-invasive rotator cuff repairs, they were difficult to execute, took a long time to learn, and required the surgeon to have exceptional skill and dexterity to perform reproducibly (or reliably). For example, because the arthroscopic procedures were performed through tubes or cannulas placed in tiny incisions in the shoulder, it was difficult to manipulate the sutures within the surgical site. This made it hard to tie suture knots. In addition, many arthroscopic repairs did not create downward pressure on the rotator cuff tendon over a wide enough area to sufficiently promote re-attachment and healing of the injury.

In 2003, KFx set out to address these and other shortcomings. KFx's patents at issue here are directed to the inventive methods KFx developed that are particularly useful in repairing torn rotator cuffs. The KFx methods made

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the surgical procedure easier to perform in a reproducible manner and also improved the strength of the repair.

In KFx's method, suture is connected between at least two anchors—a first anchor located underneath the soft tissue (the medial anchor) and a second anchor located beyond an edge of the soft tissue (the lateral anchor). The use of one or more medial anchors with one or more lateral anchors is sometimes referred to as a "double row" repair. Importantly, KFx's patented method includes the steps of tensioning the suture after inserting the lateral anchor and then fixedly securing the suture to the second anchor without tying knots. By tensioning the suture after the second anchor has been inserted into bone, the surgeon can fine-tune the degree to which the soft tissue is compressed to the bone and determine exactly how the repair will look and feel in the final construct.

In 2004, KFx filed three provisional patent applications that led to the KFx patents. In January 2006 the United States Patent and Trademark Office ("PTO") published KFx's patent application, and on September 8, 2009, the first of the three KFx patents—the '311 patent—issued. The '942 and '969 patents are continuations of the '311 patent and issued in January and February 2012, respectively. The '311 patent was later reexamined and confirmed by the PTO.

KFx worked to commercialize its concept with a product and technique called Suture Cross®. Although the product was well received by surgeons, KFx ultimately could not compete with larger companies such as Arthrex, which had large established sales organizations that were promoting techniques using KFx's patented methods.

Defendant Arthrex is the one of the largest manufacturers and suppliers of medical devices used in sports medicine in the world. Arthrex currently markets a number of knotless bone anchors that are promoted for use in performing double row procedures. Specifically, Arthrex markets the SutureBridge™

double row rotator cuff repair surgical technique ("SutureBridge"), and the SpeedBridge™ knotless double row footprint reconstruction surgical technique ("SpeedBridge"). KFx filed the instant lawsuit contending that Arthrex willfully infringes various claims of the KFx patents by actively inducing orthopedic surgeons to perform the SutureBridge and SpeedBridge procedures. KFx also contends that Arthrex contributes to the direct infringement of the KFx patents by selling kits that are especially designed for use in performing the SutureBridge and SpeedBridge procedures.

As a result of Arthrex's infringement, KFx is entitled to damages adequate to compensate KFx for the infringement, but in no event less than a reasonable royalty for the use of KFx's invention by Arthrex. Because Arthrex's infringement was and continues to be willful, the Court also may award KFx up to three times the damages awarded at trial, as well as KFx's reasonable attorneys' fees.

II. CONTENTIONS OF FACT AND LAW

A. The Teaching of the Claims of the KFx patents

The KFx patents relate to improved methods of securing soft tissue, such as tendon, to bone. For example, the KFx patents are generally directed to knotless double row repairs in which the suture pressing the tendon to the bone is tensioned after the suture anchors are inserted into bone. Shown below in Figure 3C of the '311 patent is a repaired rotator cuff with a row of anchors under the tendon and a row of anchors beyond the edge of the tendon. Sutures spanning between the anchors compresses the tendon down on its natural attachment to the bone.

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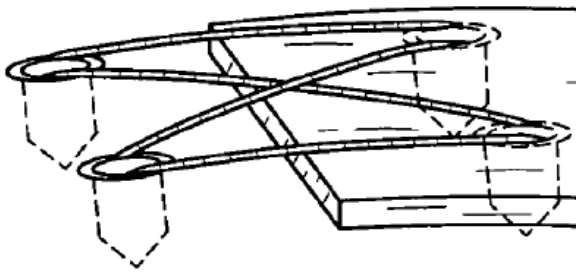

Figure 3C of the patents-in-suit depicting attachment of tendon to bone with a bridging double row procedure

The claimed methods of KFx's '311 patent generally include inserting a first anchor into the bone wherein it is located underneath the soft tissue (the "medial" anchor) and inserting a second anchor beyond the edge of the soft tissue (the "lateral" anchor). A length of suture passes through and over the soft tissue to connect the first (medial) anchor to the second (lateral) anchor. After inserting the second anchor, the suture is tensioned in order to compress the tendon to the bone surface. And finally, the suture is fixedly secured to the second anchor without tying any knots.

The claimed methods of KFx's '942 patent also include inserting a first (medial) anchor underneath the soft tissue and then passing suture over the soft tissue to a second (lateral) anchor beyond the edge of the soft tissue. The claims also recite certain details of the second anchor used in the method, namely that the second anchor comprises two parts—a distal member and a proximal member. After insertion of the distal member of the second anchor, the suture from the first (medial) anchor is tensioned to compress the soft tissue between the first anchor and the edge of the soft tissue. The proximal member of the second anchor is then moved distally towards the distal member to secure the suture at the second anchor without tying any knots.

The claimed methods of KFx's '969 patent also include inserting a first (medial) anchor underneath the soft tissue and then passing suture from the first anchor over the soft tissue. The claimed method also includes the step of inserting at least a portion of a second anchor into bone at a position beyond the

edge of the soft tissue. After insertion of the portion of the second anchor, the suture from the first (medial) anchor is tensioned to compress the soft tissue between the first anchor and the edge of the soft tissue. The suture is then fixedly secured at the second anchor position without tying knots. The claims also recite that at least one of the anchors has a hollow cylinder and an anchor tip that has an aperture through which suture can be threaded prior to insertion of the anchor.

Specific requirements of the asserted claims, including dependent claims, are set forth in greater detail below.

B. Infringement

KFx contends that Arthrex has indirectly infringed the KFx patents by actively inducing and contributing to the infringement of KFx's patents.

1. Points of Law Regarding Infringement

a. Direct Infringement

To establish induced or contributory infringement, a patentee must establish there has been a direct infringement. The use of a patented method in the United States without authority of the patent owner constitutes direct infringement. *See* 35 U.S.C. § 271(a). A patent infringement analysis is a two-step process. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1341 (Fed Cir. 2001). First, the court determines, as a matter of law, the correct claim scope. *Id.* Second, the fact-finder compares the properly construed claims to the accused product or process to determine, as a matter of fact, whether all of the claim limitations are present. *Id.*

The patentee bears the burden to establish infringement by a preponderance of the evidence. *See, e.g., Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n. 15 (Fed. Cir. 2005). To establish literal infringement, every limitation of the patent claim must be found in the accused

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method. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1231 (Fed. Cir. 2001).

Even where an accused method does not meet all of the requirements, there can still be infringement if that method satisfies the relevant patent claim under the "doctrine of equivalents." *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 22, 117 S.Ct. 1040, 1045 (1997). Under the doctrine of equivalents, a method infringes a claim if the method contains elements or performs steps that are equivalent to each and every requirement of the claim that is not literally satisfied. *See id.* An element or step is equivalent to a requirement of a claim if a person of ordinary skill in the field would have considered the differences between the element or step of the method and the claim requirements to be "insubstantial." *See id.* at 1054. Differences are insubstantial if the element or step performs substantially the same function, in substantially the same way, to achieve substantially the same result as the requirement of the claim. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 70 S.Ct. 854, 856 (1950).

To prove infringement by "equivalents," a patentee must prove the equivalency of the element or step to the requirement of the claim by a preponderance of the evidence. *See Siemens Med. Solutions USA, Inc., v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279 (Fed. Cir. 2011).

b. Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To prove induced infringement, the patentee must show by a preponderance of the evidence that the defendant acted with specific intent to induce infringement. *See DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc*). The patentee must also prove that the defendant was aware of the patent, or was willfully blind to its existence, and knew or should have known that the acts, if taken, would

constitute infringement of that patent. *Global-Tech Appliances, Inc., v. SEB, S.A.,* 563 U.S. __, 131 S.Ct. 2060, 2070 (2011). The patentee must also prove that the acts are actually carried out by the direct infringer, and that those acts directly infringe that claim. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012)

c. Contributory Infringement

To establish contributory infringement under 35 U.S.C. § 271(c), the patentee must prove by a preponderance of the evidence first that someone other than the defendant has directly infringed the patent. *See Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). The patentee must also show that the defendant sold, offered for sale, or imported within the United States a component of a product or apparatus for use in the infringing method. *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 850-51 (Fed. Cir. 2010). The patentee must also prove that the component or apparatus is not a staple article or commodity of commerce capable of substantial non-infringing use, *see Toshiba Corp.*, 681 F.3d at 1362, and that the component or apparatus constitutes a material part of the patented invention, *Fujitsu*, 620 F.3d at 1326. Finally, the patentee must prove that the defendant knew that the component or apparatus was especially made or adapted for use in an infringing method. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 84 S.Ct. 1526, 1533 (1964).

2. Claim Construction

On September 10, 2012, this Court construed disputed terms of the KFx patents. D.I. 64. The Court ruled that the phrase "inserting a [ ] anchor into bone" should be construed according to its plain and ordinary meaning, namely "inserting" means putting or placing into. Thus, "inserting a [ ] anchor into bone" means putting or placing the anchor into bone.

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The term "suture" was construed by the Court to mean "any flexible structure that can be stretched between two or more anchors, and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure."

The Court construed the phrase "fixedly securing the first length of suture to the second anchor without tying knots" to mean "the first length of suture cannot be easily moved relative to the second anchor and that this step is completed without tying any knots."

With respect to the '942 patent, the Court concluded that the phrase "moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots" should be construed according to its plain and ordinary meaning.

With respect to the '969 patent, the Court found that the phrase "inserting at least a portion of a second anchor into bone at a position beyond the edge of the soft tissue" [together with] "fixedly securing the first length of suture at the second anchor position without tying any knots" should be construed according to its plain and ordinary meaning.

The Court also concluded that the phrase "at least one of said anchors" should be construed according to its plain and ordinary meaning.

3. <u>The Accused SutureBridge and SpeedBridge Methods</u>

Arthrex markets two rotator cuff procedures that are accused of infringing the KFx patents, the SutureBridge and SpeedBridge rotator cuff repair procedures. Arthrex instructs surgeons on how to perform the procedures in a variety of ways, including instructional videos and animations, published technique guides, etc. And, of course, Arthrex sells various products to be used in performing the procedures, including anchors, sutures and other

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instruments. Performance of the SutureBridge and SpeedBridge procedures by orthopedic surgeons directly infringes the asserted claims of the KFx patents.

The procedures have a number of common features. As taught and promoted by Arthrex, the procedures each include two medial anchors located under the soft tissue (rotator cuff tendon) that is to be reattached to the bone. Sutures are brought from the medial anchors through the soft tissue and over the edge of the soft tissue. In performing the procedures as taught by Arthrex, the lateral anchors are inserted into the bone at a position beyond the edge of the soft tissue, the sutures from the medial anchors are tensioned, and the sutures are then fixedly secured to the lateral anchors without tying knots.

The two Arthrex procedures vary in the type of anchors that are used. The SutureBridge procedure generally uses two Corkscrew suture anchors in the medial position and two PushLock suture anchors in the lateral position. The SpeedBridge procedure generally uses four SwiveLock suture anchors – two each in the medial and lateral position.[1]

The PushLock and SwiveLock anchors used in the SutureBridge and SpeedBridge techniques are knotless anchors that share several common features. They are both two-piece anchors with a distal eyelet portion and a proximal body portion. The anchors are arranged on the end of a driver to facilitate their insertion.

The sutures from the medial anchors are threaded through the eyelet portions of the PushLock anchor (for SutureBridge) or SwiveLock anchor (for SpeedBridge), the eyelet portions of the anchors are then inserted into the bone at the lateral positions, the sutures are then tensioned, and then the body portions of the anchors are inserted to secure the sutures without tying knots.

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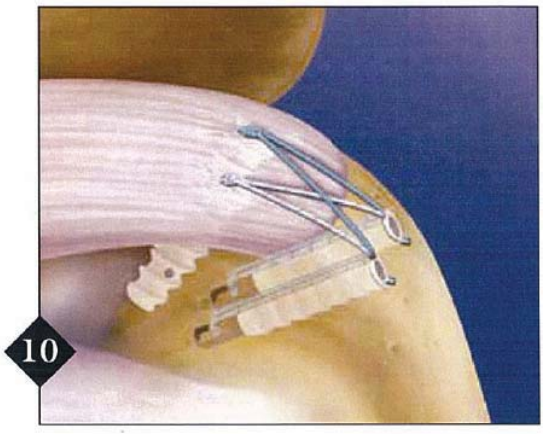
[1] SwiveLocks are also promoted as an alternative anchor for use in the lateral position instead of PushLocks in a SutureBridge procedure.

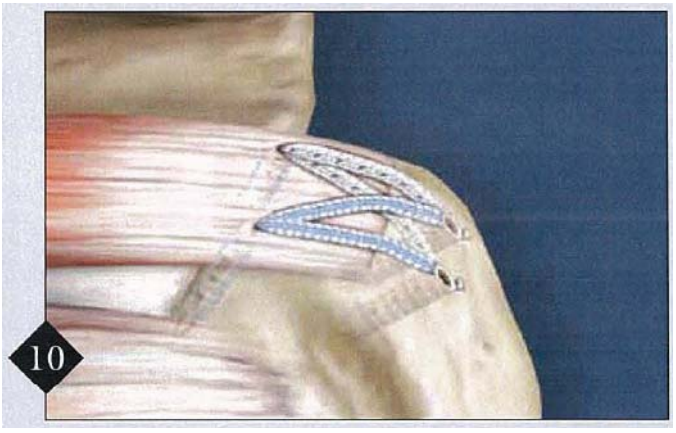
A few claim elements are common to KFx's asserted patent claims. Although the language of those elements varies somewhat across different claims, KFx will present similar evidence to demonstrate that the accused procedures include those elements. The manner in which SutureBridge and SpeeBridge satisfy these claim elements is described below.

a. Medial anchors are inserted into bone underneath the soft tissue

KFx will present evidence to show that, in performing either the SutureBridge procedure (completed repair shown below left) or SpeedBridge procedure (completed repair shown below right), medial anchors are inserted into bone such that they are positioned entirely underneath the soft tissue. Arthrex's argument to the contrary is based on an erroneous and untimely claim construction argument, wherein Arthrex contends the KFx patent claims require the anchors to be inserted through the soft tissue. This claim construction argument is addressed in detail in KFx's opposition to Arthrex's pending summary judgment motion.



***Arthrex SutureBridge Double Row Rotator Cuff Repair Surgical Technique Guide* © 2011 ("SutureBridge Technique Guide"), p. 5, illustration for step 10**



***Arthrex SpeedBridge and SpeedFix Knotless Rotator Cuff Repair using the SwiveLock C and FiberTape* © 2010 ("SpeedBridge Technique Guide"), p. 5, illustration for step 10**

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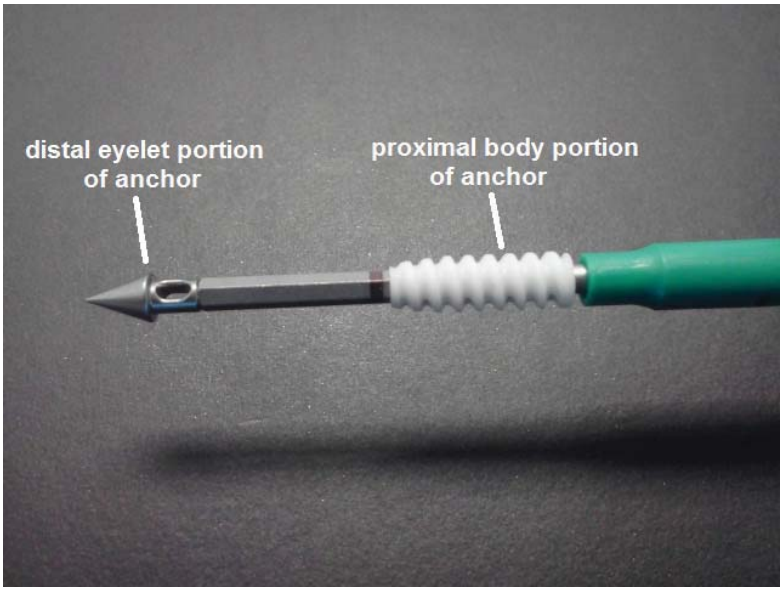
b. The distal eyelet portion is part of the Arthrex anchors

To avoid the claim step of tensioning after insertion of the second (lateral) anchor (or portion thereof) as recited in KFx's patents, Arthrex has argued that the eyelet portion of the PushLock and SwiveLock anchors are not actually part of the anchor. KFx will present evidence to show that the PushLock and SwiveLock anchors are two-piece anchors. Shown below are the two components of an exemplary SwiveLock Self-Punching (SP) anchor arranged on a driver. Both the distal eyelet anchor portion and the proximal anchor body portion are parts of a single device – an anchor.



SwiveLock SP Self Punching Anchor shown positioned on anchor inserter

To the extent Arthrex maintains its argument that the eyelet portion is not part of the SwiveLock or PushLock anchors, KFx will present voluminous evidence, including Arthrex's surgical videos available on its website, as well as materials and documents produced by Arthrex, to show that the distal eyelet portion of the PushLock and SwiveLock is part of the anchor. These materials include Arthrex emails, the Design History Files of the anchors, Arthrex communications with regulatory bodies such as the FDA regarding the anchors, Arthrex's surgical technique guides, and other publications and materials. For example, in a video titled *SutureBridge® Rotator Cuff Repair Featuring the*

PushLock® Anchor, performed and narrated by Dr. Neal ElAttrache and available on Arthrex's website, Dr. ElAttrache refers to threading suture through the "eyelet of the anchor" and "advancing the anchor into my pilot hole" when placing the distal eyelet anchor portion into the hole. KFx will also present evidence that Arthrex engineers, product managers, regulatory specialists, and other employees have represented that the PushLock and SwiveLock anchors are two-piece anchors.

c. <u>The suture is tensioned after the eyelet of the lateral anchor is inserted into the bone hole</u>

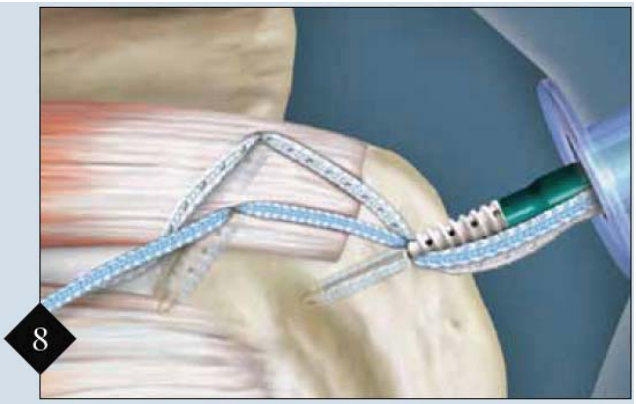
In an attempt to avoid the claim step of tensioning after insertion of the second (lateral) anchor or a portion thereof, as recited in KFx's patents, Arthrex also has argued that surgeons only tension the suture prior to inserting the lateral anchor or a portion thereof into the bone hole. KFx will present evidence to show that is not the case. Use of the PushLock and SwiveLock anchors in the lateral row of the SutureBridge and SpeedBridge procedures, respectively, includes tensioning the suture after inserting the distal eyelet portion of the anchor into bone. This is confirmed by voluminous evidence, including Arthrex emails and other communications, Arthrex's surgical technique guides, as well as Arthrex's surgical videos and animations.

For example, in a video titled *Arthroscopic SpeedBridge™ Double Row Rotator Cuff Repair*, performed and narrated by Dr. Peter Millett and available on Arthrex's website, Dr. Millett states, "what I usually do is put a little bit extra slack in the system; I put it in loose initially." Then, after inserting the eyelet into the bottom of the hole, Dr. Millet says "now what we can do is tension the sutures individually. ***This is really an important point, important part of this procedure*** – you can see it tightening up." (Emphasis added.)

Similarly, Dr. ElAttrache explicitly discusses tensioning the sutures after insertion in his SutureBridge video featured on Arthrex's website.

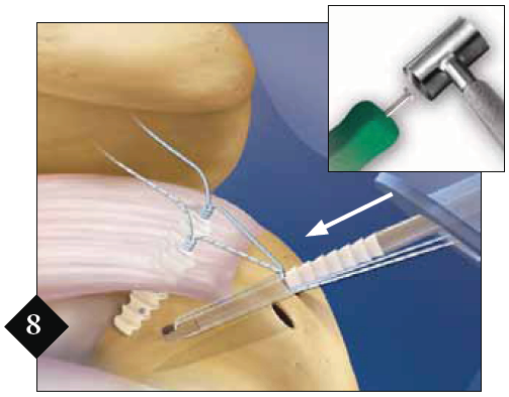
Dr. ElAttrache states, after showing the eyelet inserted in bone, "what I can do at this stage is individually tension these stitches as necessary. I'm going to give a little tug on the blue stitch. You just pull a little bit on that blue stitch. Which if you could see that, that pulled down just a little bit."

Arthrex's published technique guides (excerpts below) also teach tensioning the sutures after insertion of the second (lateral) anchor. For example, Arthrex's SpeedBridge technique guide (below left) instructs surgeons to insert the SwiveLock anchor into the prepared lateral bone socket and then "[a]djust tension of each FiberTape limb individually." Additionally, Arthrex's SutureBridge Technique guide (below right) instructs that "additional tension may be applied, while leaving the driver in place, by pulling on each suture strand independently."



Insert the Bio-SwiveLock C into the prepared lateral bone socket until the anchor body contacts bone. Adjust tension of each FiberTape limb individually.

SpeedBridge Technique Guide, p. 5, step 8



Completely advance the driver into the pilot hole beyond the first laser line, until the anchor body contacts bone. Evaluate tissue tension. If it is determined that the tension is not adequate, the driver can be backed out and tension readjusted. Alternatively, additional tension may be applied, while leaving the driver in place, by pulling on each suture strand independently.

Use a mallet to tap the anchor body into the pilot hole until the second laser line is flush with the humerus.

SutureBridge Technique Guide, p. 4, step 8

d. <u>The suture is fixedly secured to the lateral anchor without tying knots</u>

In Arthrex's SutureBridge technique, knots are tied above the medial anchors. Arthrex has argued that the knots over the medial anchors avoid the

claim step of fixedly securing suture to the second (lateral) anchor without tying knots as recited in KFx's patents. This contention is meritless because the plain language of the claim precludes knots during the step of securing the sutures *to the second anchor*, not the first (medial) anchor.

As set forth above, the Court has construed the phrase "fixedly securing the first length of suture to the second anchor without tying knots" to mean "the first length of suture cannot be easily moved relative to the second anchor and that this step is completed without tying any knots." KFx will present evidence that the step of securing the sutures to the second (lateral) anchors is done without knots, that Arthrex recognizes this as a knotless step, and the medial knots in the SutureBridge are not necessary to fixedly secure the sutures to the lateral anchor.

4. <u>The accused procedures directly infringe the asserted claims of the '311 patent</u>

KFx alleges that use of the SutureBridge and SpeedBridge procedures directly infringes claims 1, 5-7, 11, 12, 14-20, 23-25, and 28-30 of the '311 patent, and that use of the SpeedBridge procedure also directly infringes claim 21 of the '311 patent. KFx will present evidence through testimony of its technical expert, Dr. Jonathan Ticker, testimony of Arthrex's employees, Arthrex's documents and other materials, and Arthrex's surgical animations and videos that surgeons directly infringe the asserted claims of the '311 patent when performing the SutureBridge or SpeedBridge procedures.

a. <u>'311 Patent – Independent Claim 1</u>

Claim 1 recites:

> *A method of attaching soft tissue to bone, comprising:*
>
> **[1]** *inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue;*

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> **[2]** *passing a first length of suture from said first anchor over the soft tissue;*
>
> **[3]** *inserting a second anchor into bone, wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue;*
>
> **[4]** *after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and*
>
> **[5]** *fixedly securing the first length of suture to the second anchor without tying any knots.*

KFx will present evidence that each limitation of the five steps of the method of Claim 1 is performed when Arthrex's customers practice the SutureBridge and SpeedBridge procedures as taught by Arthrex.

First, a first anchor is inserted into bone such that it is positioned underneath the soft tissue and that no part of the anchor extends beyond an edge of the soft tissue.

Second, a length of suture is passed over the tendon.

Third, a second anchor is inserted into bone so that it is positioned beyond the edge of the soft tissue and is not underneath the soft tissue, as shown below in the excerpts of the SutureBridge and SpeedBridge technique guides.

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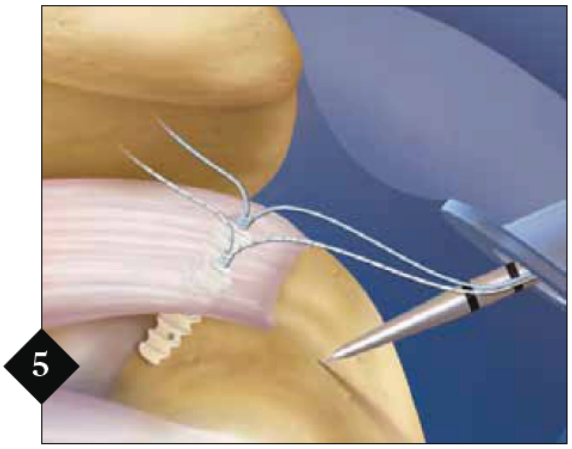
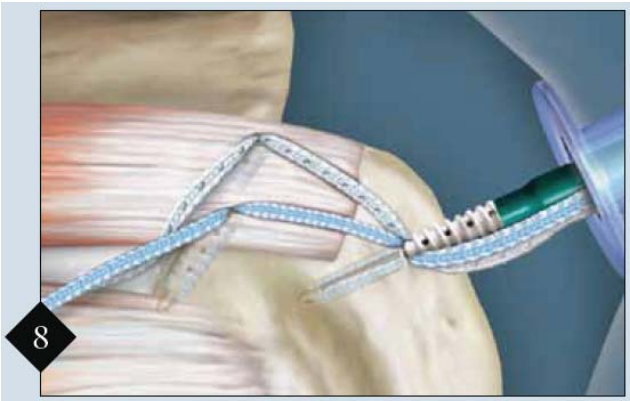


Tie the medial row but do not cut the FiberWire® tails. These tails will be draped over the lateral aspect of the tendon and held in place with two knotless PushLock anchors.

Prepare pilot holes for the BioComposite PushLock (or alternatively SwiveLock) directly in line with the medial anchors and approximately 5-10 mm distal to the lateral edge of the greater tuberosity. It may be necessary to increase abduction or to rotate the arm for optimal PushLock placement.

SutureBridge Technique Guide, p. 4, step 5



Insert the Bio-SwiveLock C into the prepared lateral bone socket until the anchor body contacts bone. Adjust tension of each FiberTape limb individually.

SpeedBridge Technique Guide, p. 5, step 8

Fourth, as explained above, the length of suture (*i.e.*, suture from the first, medial, anchor) is tensioned to compress an area of tissue to bone between the edge of soft tissue and the first anchor after the second anchor is inserted.

Finally, the suture is fixedly secured to the second anchor without tying any knots.

b. ’311 Patent – Dependent Claims 5-7, 11, 12, 14-21, 23-25, and 28-30

Claim 1 recites a procedure with one medial anchor and one lateral anchor. The dependent claims add additional details to this basic repair method. Claims 5-7 include a second lateral anchor. Claims 11, 12, and 14 include a second medial anchor, which is referred to as the third anchor in the claims. Claims 15-19 include a second lateral anchor, which is referred to as the fourth anchor in the claims. Claim 20 includes four anchors (two medial and two lateral) and adds an additional requirement that the suture passing from the

second medial anchor to the second lateral anchor crosses over the other suture passing from the first medial anchor to the first lateral anchor. Claim 21 addresses insertion of the first anchor and claim 23 further addresses the step of passing suture over the soft tissue. Claims 24 and 25 involve insertion of the second anchor. Claim 28 requires that certain claimed steps are performed arthroscopically. Finally, Claims 29 and 30 recite how the first length of suture passes through and over the soft tissue.

KFx will also present evidence, including Arthrex technique guides, Arthrex's animations, Arthrex website surgical videos, Arthrex documents and physical exhibits, and the testimony of KFx's expert, Dr. Ticker, to show that the accused procedures perform the steps recited in these dependent claims.

5. The accused procedures directly infringe the asserted claims of the '942 patent

KFx alleges that use of the SutureBridge and SpeedBridge procedures both directly infringe claims 1-7, 11-13, and 15-19 of the '942 patent, that use of the SutureBridge procedure also directly infringes claims 9 and 10 of the '942 patent, and that use of the SpeedBridge procedure directly infringes claim 14 of the '942 patent. KFx will present evidence through testimony of its technical expert, Dr. Jonathan Ticker, testimony of Arthrex's employees, Arthrex's documents and other materials, and Arthrex's surgical animations and videos that surgeons directly infringe the asserted claims of the '942 patent when performing the SutureBridge or SpeedBridge procedures.

The asserted claims of the '942 patent include steps that are similar to the steps of the asserted claims of the '311. Both patents claim a method of attaching soft tissue to bone using a first (medial) and a second (lateral) anchor, with suture passing from the first anchor through and over the soft tissue to the second anchor. The asserted claims of both patents also involve tensioning the suture after inserting the second anchor or a portion of the second anchor into

the bone and then fixedly securing the suture to the second anchor. The '942 patent further addresses particular configurations of the second anchor as well as use of an anchor inserter to perform certain steps of the claimed method, as discussed further below.

a. '942 Patent – Independent Claim 1

Claim 1 recites:

> *A method of attaching soft tissue to bone, comprising:*
> **[1]** *inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;*
> **[2]** *passing a first length of suture from said first anchor over the soft tissue;*
> **[3]** *inserting a distal member of a second anchor into bone at a position beyond an edge of the soft tissue, wherein the second anchor comprises said distal member and a proximal member;*
> **[4]** *after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and*
> **[5]** *after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots.*

KFx will present evidence to show that each limitation of the five steps of the method of Claim 1 of the '942 patent is performed when Arthrex's customers practice the SutureBridge and SpeedBridge procedures as taught by Arthrex.

First, a first anchor is inserted into bone such that it is positioned underneath the soft tissue.

Second, suture is passed through and over the rotator cuff tissue.

Third, the second (lateral) anchor of the SutureBridge and SpeedBridge procedures, the SwiveLock and PushLock anchors, includes a distal member and a proximal member, as described above. The accused procedures each

include the step of inserting the distal member of the second (lateral) at a position beyond an edge of the soft tissue.

Fourth, after inserting the distal member of the second anchor, the length of suture from the first (medial) anchor is tensioned to compress an area of tissue to bone between the edge of the soft tissue and the first anchor.

Fifth and finally, the techniques each include the step of fixedly securing the length of suture at the second anchor position without tying any knots.

b. ’942 Patent – Dependent Claims 2-7 and 9-18

Claim 1 recites a basic rotator cuff procedure with one medial anchor and one lateral anchor. The dependent claims of the ’942 patent add additional features to the method. Claims 2 and 3 recite details regarding the manner in which the medial and lateral anchors are inserted. Claims 4-12 recite additional features of the medial and lateral anchors used in the procedures. Claims 13-15 recite using an anchor inserter to perform the procedure. Claims 16 and 17 recite coupling suture to an anchor and tensioning the suture. Claim 18 includes a second medial anchor, which is referred to as the third anchor in the claim.

KFx will also present evidence, including Arthrex documents, physical exhibits, Arthrex website animations and videos, technique guides, and the testimony of KFx’s expert, Dr. Ticker, to show that the accused procedures perform the steps and use anchors according to the configurations recited in these dependent claims.

c. ’942 patent – Independent Claim 19

The ’942 patent includes a second independent claim (Claim 19), which recites the following method:

> *A method of attaching soft tissue to bone, comprising:*
>
> **[1]** *inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;*
>
> **[2]** *passing a first length of suture from said first anchor over the soft tissue;*

> **[3a]** *coupling the first length of suture to a second anchor, wherein the second anchor comprises a distal member and a proximal member, wherein said proximal member is cylindrically shaped and comprises a central bore extending therethrough;*
>
> **[3b]** *after coupling the first length of suture to the second anchor, inserting the distal member of the second anchor into bone at a position beyond an edge of the soft tissue;*
>
> **[4]** *after inserting the distal member of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and*
>
> **[5]** *after tensioning the first length of suture, moving the proximal member of the second anchor distally towards the distal member of the second anchor, thereby fixedly securing the first length of suture at the second anchor position without tying any knots, wherein inserting the distal member of the second anchor and moving the proximal member of the second anchor distally toward the distal member comprises using an anchor inserter comprising a handle, a tube, and an inner member, wherein the inner member extends through the tube and the central bore in the proximal member of the second anchor and is removably coupled to the distal member of the second anchor.*

Claim 19 incorporates many of the elements of claim 1 of the ’942 patent and its dependent claims, including claims 11-13, in that it addresses using an anchor inserter for a procedure with one medial anchor and one lateral anchor. The same sources of evidence discussed above regarding other asserted claims of the ’942 patent can and will be used to demonstrate that the SutureBridge and SpeedBridge procedures directly infringe this claim.

6. <u>The accused procedures directly infringe the asserted claims of the ’969 patent</u>

KFx alleges that use of the SutureBridge and SpeedBridge procedures directly infringe Claims 1, 3, 4, and 14-16 of the ’969 patent, that use of the SutureBridge procedure directly infringes claims 5-7 of the ’969 patent, and that use of the SpeedBridge procedure directly infringes claims 2, 13, and 17 of the ’969 patent. KFx will present evidence through testimony of its technical

expert, Dr. Jonathan Ticker, testimony of Arthrex's employees, Arthrex's documents and other materials, and Arthrex's surgical animations and videos that surgeons directly infringe the asserted claims of the '969 patent when performing the SutureBridge or SpeedBridge procedures.

The asserted claims of the '969 patent include steps that are similar to the asserted claims of the '311 and '942 patents as described above, namely (1) inserting a first anchor such that it is positioned under the soft tissue, (2) passing a length of suture from the first anchor over the soft tissue, (3) inserting at least a portion of a second anchor into bone at a position beyond the edge of the soft tissue, (4) tensioning the suture from the first anchor, and (5) fixedly securing the suture to the second anchor without tying knots. The '969 patent further addresses particular features of an anchor to be used in the method, as discussed further below.

a. '969 Patent – Independent Claim 1

Claim 1 recites:

A method of attaching soft tissue to bone, comprising:

[1] *inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;*

[2] *passing a first length of suture from said first anchor over the soft tissue;*

[3] *inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue;*

[4] *after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and*

[5] *after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;*

[*] *wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises an aperture through which suture material is threaded prior to insertion of the at least one anchor.*

KFx will present evidence to show that each limitation of the five steps of the method of Claim 1 of the '969 patent is performed when Arthrex's customers practice the SutureBridge and SpeedBridge procedures as taught by Arthrex.

KFx will also present evidence that the PushLock and SwiveLock anchors also include the features recited in the last paragraph of Claim 1 (identified as [*] above), namely the anchors each include an anchor tip (distal eyelet portion of the anchor) and a hollow cylinder (body portion of the anchor) and the distal eyelet portion comprises an aperture through which suture material is threaded prior to insertion of the anchor.

b. <u>'969 Patent – Dependent Claims 2-7 and 13-16</u>

Claim 1 recites a procedure with one medial anchor and one lateral anchor. Claims 2-3 include more specific features of the anchors used in the procedures. Claims 4-7 and 13 recite using an anchor inserter to perform the procedure. Claim 14 includes coupling suture to an anchor and claim 15 recites tensioning the suture. Claim 16 includes a second medial anchor, which is referred to as the third anchor in the claim.

KFx will also present evidence, including Arthrex documents, physical exhibits, Arthrex website animations and surgical videos, surgical technique guides, and the testimony of KFx's expert, Dr. Ticker, to show that the accused procedures perform the steps and use anchors according to the configurations recited in these dependent claims.

c. <u>'969 Patent – Independent Claim 17</u>

Claim 17 recites:

> *A method of attaching soft tissue to bone, comprising:*
>
> **[1]** *inserting a first anchor into bone, wherein after insertion, the first anchor is positioned underneath the soft tissue;*
>
> **[2]** *passing a first length of suture from said first anchor over the soft tissue;*

> **[3]** *inserting at least a portion of a second anchor into bone at a position beyond an edge of the soft tissue;*
>
> **[4]** *after inserting said at least a portion of the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and*
>
> **[5]** *after tensioning the first length of suture, fixedly securing the first length of suture at the second anchor position without tying any knots;*
>
> **[*]** *wherein at least one of said anchors comprises an anchor tip and a hollow cylinder, wherein the anchor tip comprises:*
>
> *an aperture through which suture material is threaded prior to insertion of the at least one anchor,*
>
> *an engaging member adapted to engage an inner surface of said cylinder, and*
>
> *an anchor inserter attachment member, wherein insertion of the at least one anchor comprising an anchor tip and a hollow cylinder comprises using an inserter that comprises a handle, an outer sleeve, and an inner member, wherein the inner member extends through the outer sleeve and the hollow cylinder and is attached to the anchor inserter attachment member.*

This claim is similar to claim 1 of the '969 patent and dependent claims 2-4 in that Claim 17 addresses using an anchor inserter for a procedure with one medial anchor and one lateral anchor. The same sources of evidence discussed above regarding the other asserted claims of the '969 patent can and will be used to demonstrate that the SutureBridge and SpeedBridge procedures directly infringe this claim.

To the extent any claim limitation of any of the asserted claims is not literally present in the accused methods, it is satisfied by an equivalent under the doctrine of equivalents.

7. <u>Material Facts Regarding Induced Infringement</u>

As described above, KFx will present evidence that Arthrex's SutureBridge and SpeedBridge procedures infringe the asserted claims of the

KFx patents. KFx will also present evidence that Arthrex actively and knowingly aided and abetted the direct infringers and actually intended to cause the infringement. KFx will show this through, among other things, the testimony of KFx's expert, Dr. Ticker, the testimony of Arthrex's employees as well as Arthrex's own documents and promotional materials.

Arthrex has undertaken many actions evidencing its intent to cause the direct infringement of the KFx patents. For example, Arthrex's website contains multiple technique guides, animations, and surgical videos that demonstrate for surgeons visually and verbally how to perform the SutureBridge and SpeedBridge procedures in manners that infringe the asserted claims of the KFx patents. Arthrex extensively trains its sales representatives to teach surgeons the SutureBridge and SpeedBridge procedures. Additionally, Arthrex provides Directions for Use for the individual products used in performance of the accused procedures and has run multiple advertisements for these procedures. All of these actions constitute active steps taken by Arthrex, or on behalf of Arthrex with Arthrex's knowledge and approval, to cause direct infringement of the KFx patents.

KFx will also present evidence that Arthrex knew of the KFx patents and that Arthrex knew or should have known that its actions would lead to the direct infringement. KFx will show this through the testimony of Arthrex's employees, as well as Arthrex's own documents and emails.

[redacted]

[redacted]

KFx will also present evidence to show that Arthrex knew or should have known that its SutureBridge and SpeedBridge procedures infringed the KFx patents. KFx will present evidence to show that when KFx's '311 patent issued, Arthrex knew or should have known that the patent covered its SutureBridge and SpeedBridge procedures. Similarly, when KFx's '942 and '969 patents issued, Arthrex was already aware of its infringement of the '311 patent by virtue of this lawsuit, and therefore knew or should have known it also infringed the '942 and '969 patents.

8. Material Facts Regarding Contributory Infringement

KFx will also present evidence that Arthrex's SutureBridge kits and Arthrex's SpeedBridge kits have no substantial noninfringing use and that the components of the kits constitute a material part of KFx's claimed inventions. KFx will also present evidence through the testimony of Arthrex employees, as well as Arthrex's own documents and emails that Arthrex knew of KFx's asserted patents that Arthrex knew or should have known that its actions would lead to the direct infringement thereof.

C. Damages

1. Points of Law Regarding Damages

Once liability for infringement has been established, a patentee is entitled to damages adequate to compensate the patentee for the infringement, which shall be no less than a reasonable royalty. 35 U.S.C. § 284.

A reasonable royalty is determined based upon a hypothetical negotiation between a willing licensor and a willing licensee occurring just before infringement began. *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1312 (Fed. Cir. 2011) (citing *Wang Labs. Inc. v. Toshiba Corp.*, 993 F.2d 858,

869-70 (Fed. Cir. 1993)). An established method of evaluating the likely outcome of this hypothetical negotiation is to consider the 15 factors set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

2. Material Facts Regarding Damages

KFx seeks a reasonable royalty on Arthrex's sales of its accused products used in the accused procedures. To date, KFx has received information regarding Arthrex's sales of those products through the end of 2012.

KFx's damages expert, Mr. George Strong, will testify that KFx is entitled to [redacted] for sales through 2012. This equals 11.7% of Arthrex's revenue from anchors used in the infringing procedures. In order to determine damages from January 2013 through trial, Mr. Strong will use updated sales information produced by Arthrex and/or extrapolate from the 2012 data that he has received. KFx will also seek an accounting for damages due to any infringing sales from trial forward. Finally, KFx will seek prejudgment and postjudgment interest on any damages award.

To determine the amount of damages owed to KFx, Mr. Strong first determined the number of accused procedures performed by surgeons using Arthrex's products. Although Arthrex does not formally track the number of those procedures, Arthrex has estimated the number of those procedures at various times in the normal course of its business based upon certain assumptions. Mr. Strong will testify that, using Arthrex's estimates and assumptions, as well as a regression analysis, he determined the anchor sales associated with the infringing procedures. Mr. Strong also determined the profits that Arthrex earned from selling anchors for use in those procedures.

Mr. Strong will also rely on Dr. Ticker, who is an orthopedic surgeon specializing in shoulder surgery and KFx's medical expert. Dr. Ticker will testify regarding the types of procedures that would have been available

alternatives had the accused procedures not been available, *i.e.*, "but for" the infringement. Dr. Ticker will also testify regarding the frequency with which surgeons would have been expected at the time of the hypothetical negotiation to perform the various alternative procedures, each of which used a different number and type of anchors. Based on Dr. Ticker's determinations, Mr. Strong calculated the incremental profits that KFx earned from selling anchors to be used in the accused procedures instead of the alternative procedures.

Mr. Strong will further testify that parties to a hypothetical negotiation would have determined a reasonable royalty based on that incremental profit. Mr. Strong will testify that, after considering the *Georgia Pacific* factors, an equal division of the incremental profits is the proper measure of a reasonable royalty in this case.

D. Willful Infringement

1. Points of Law Regarding Willful Infringement

Upon a finding of infringement and assessment of damages against the infringer, 35 U.S.C. § 284 provides that "the court may increase the damages up to three times the amount found or assessed." An award of enhanced damages requires a showing of willful infringement. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (*en banc*) (citing *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1578 (Fed. Cir. 1991)).

The test for willful infringement includes both an objective prong and a subjective prong. *Seagate*, 497 F.3d at 1371. First, the patentee must show by clear and convincing evidence that the defendant, with knowledge of the asserted patent, acted despite an objectively high likelihood that its actions constituted infringement. *Id.* This determination is ultimately a question of law. *Id.* But if an accused infringer's defense to willful infringement involves questions of fact, or mixed questions of law and fact, the fact-finder may determine the underlying facts relevant to the defense in the first instance. *Bard*

Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc., 682 F.3d 1003, 1007-08 (Fed. Cir. 2012). If the threshold objective prong is satisfied, the patentee must then prove that the objectively high risk was either known or so obvious that it should have been known to the defendant. *Seagate*, 497 F.3d at 1371.

2. Material Facts Regarding Willful Infringement

KFx will present evidence at trial to show that Arthrex was, and always has been, aware of the KFx patents, including at least the '311 patent from long before its issuance on September 8, 2009. KFx will also establish that there was an objective high likelihood that Arthrex's SutureBridge and SpeedBridge procedures infringe KFx's patents and that such patents were and are valid. KFx will also show that the objectively high risk of infringement was either known to Arthrex or so obvious that Arthrex should have known of the risk.

KFx will show that despite Arthrex's knowledge of the risk that its SutureBridge and SpeedBridge procedures infringe KFx '311 patent, Arthrex did nothing to change its business practices and instead chose to continue violating KFx's intellectual property rights until KFx was forced to file this lawsuit. KFx understands that Arthrex intends to point to certain legal opinion letters it obtained well after this lawsuit was filed and years after KFx's '311 patent issued. To the extent necessary, KFx will show that the opinion letters were untimely and therefore cannot negate Arthrex's knowledge of the objective high risk of infringement. KFx will also establish that the opinions, even if they had been timely, were so fundamentally flawed that they could not have given Arthrex any reasonable basis to conclude it was not infringing KFx's patents.

E. Anticipation

1. Points of Law Regarding Anticipation

To establish that the asserted claims of KFx's patents are invalid based upon anticipation, Arthrex must show by clear and convincing evidence that the claimed inventions are not new. 35 U.S.C. § 282; *TypeRight Keyboard Corp. v.*

Microsoft Corp., 374 F.3d 1151, 1157 (Fed. Cir. 2004). For a claim to be invalid because it is not new, Arthrex must show that a single item of prior art discloses all elements of the claim, and those elements must be "arranged as in the claim." *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

2. Material Facts Regarding Anticipation

Arthrex contends that a collection of items it labels the "ElAttrache/Arthrex work" anticipates certain asserted claims. The work generally involved the use of a Bio-Tenodesis screw as an anchor in possible rotator cuff repairs. Arthrex cannot meet its burden of showing anticipation for numerous reasons. First, the work does not qualify as prior art and, for the most part, does not predate KFx's invention. Second, the work did not include every limitation of any claims of the KFx patents. For example, it did not include the step of tensioning suture after insertion of a second anchor or any portion or member of the second anchor into bone. Tensioning did not and cannot occur after insertion of the Bio-Tenodesis anchor. Further, the technique included knots tied over the Bio-Tenodesis screws to secure the suture to the second or lateral anchor. The technique also did not include various additional limitations, including, without limitation, the requirement of a proximal and distal member of a second or lateral anchor, the step of fixedly securing the suture at the second anchor position by moving the proximal member of the second anchor distally towards the distal member of the second anchor. Indeed, because, the Bio-Tenodesis is a single-piece anchor consisting of an interference screw, it cannot meet any of the limitations requiring a two piece anchor.

F. Obviousness

1. Points of Law Regarding Obviousness

To establish that the asserted claims of the KFx patents are invalid as obvious in view of the prior art, Arthrex must show by clear and convincing

evidence that the claimed invention would have been obvious to persons of ordinary skill in the art at the time the invention was made. Obviousness is a question of law based on underlying factual findings known as the *Graham* factors: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art at the time the invention was made; and (4) "secondary considerations" or "objective evidence" of nonobviousness. *See Osram Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012).

Objective evidence of nonobviousness includes evidence of copying, commercial success, praise by others, failure of others and long-felt need. *See Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372 (Fed. Cir. 2012). The *Graham* factors encompass a number of other subsidiary factual issues, including "[w]hat a reference teaches, whether there is a trend or demand in the relevant marketplace or design community, [and] the background knowledge of one of skill in the art." *TriMed, Inc. v. Stryker, Corp.*, 608 F.3d 1333, 1341 (Fed. Cir. 2010).

2. Material Facts Regarding Obviousness

KFx will demonstrate that Arthrex has failed to carry its burden of proof by clear and convincing evidence. Specifically, KFx will show that Arthrex's alleged prior art does not teach or otherwise suggest the invention recited in the claims of the KFx patents, and there is no reason to combine the various prior art references in the manner Arthrex alleges.

For example, KFx will present evidence to show that it would not have been obvious for a person of ordinary skill in the art, prior to the time of its inventions, to modify the ElAttrache/Arthrex work or combine features thereof with the Millett work, the Thal '168 patent, the Burkhart '272 patent, the ElAttrache '281 patent, the Bio-Tenodesis screw, the Guanche work, the Greenfield '835 patent, the Thal '904 publication, or any other prior art

references to arrive at the inventions of the KFx patents. KFx will also present evidence to show that the Millett work does not describe using knotless anchors, and it would not have been obvious to modify or combine the Millett work with knotless lateral anchors to arrive at the claimed invention. Such a modification is pure hindsight.

Moreover, KFx will present evidence at trial to show that even if knotless double row repairs were obvious in 2004, Arthrex cannot prove that it would have been obvious at the time to perform the method as claimed in the KFx patents. For example, Arthrex cannot prove that the step of tensioning the suture after insertion of the lateral anchor into bone was obvious in 2004. In fact, KFx will present evidence to show that Arthrex itself did not appreciate this advantage until December 2005.

KFx will also present evidence regarding the secondary considerations of non-obviousness, including evidence from one or more of the inventors of the KFx patents and expert testimony from Dr. Ticker that the inventions of the KFx patents met a long-felt but unresolved need. For example, KFx will present evidence to show that there was a long-felt need for an arthroscopic rotator cuff repair solution that would decrease retear rates, and allow reproducible, knotless fixation. KFx will also present evidence that its patented methods have been commercially successful as a result of the patented features. KFx also will present evidence at trial to show that Arthrex recognized a need for KFx's invention after KFx had made its invention and also praised KFx's invention, albeit, unknowingly, when Arthrex attempted to patent a method for knotless double row procedures in February 2006.

Finally, KFx will show that some alleged references do not predate the KFx invention and therefore do not qualify as prior art.

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G. Defenses Under 35 U.S.C. §112 (Written Description, Enablement and Best Mode)

1. Points of Law Under 35 U.S.C. §112 Defenses

a. Written Description

To establish that a claim is invalid under 35 U.S.C. §112 for failing to comply with the written description requirement, an accused infringer must show by clear and convincing evidence that the written description of the invention in the patent is not adequate. *Ariad Pharms., Inc. v. Eli Lilly And Co.*, 598 F.3d 1336, 1354 (Fed. Cir. 2010) (*en banc*). The written description requirement is satisfied if a person of ordinary skill reading the patent specification would recognize that it describes the invention as it is finally claimed in the issued patent. *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012). It is unnecessary to spell out every detail of the invention in the specification and specific examples are not required. *Id.*

b. Enablement

An accused infringer bears the burden of establishing lack of enablement by clear and convincing evidence. *Streck*, 665 F.3d at 1288. To satisfy the enablement requirement, a patentee must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention at the time the patent application was filed, to make and use the full scope of the claimed invention without undue experimentation. *Id.* A patent need not expressly state information that a person of ordinary skill would be likely to know or could obtain. *Id.* The fact that some experimentation may be required for a person of ordinary skill in the art to practice the claimed invention does not mean that the patent fails to meet the enablement requirement. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

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c. Best Mode

The Leahy-Smith America Invents Act ("AIA") made a number of changes to the U.S. patent laws, and as a result a patentee's failure to disclose a best mode is no longer a basis for invalidating an issued patent. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 15, 125 Stat. 284, 328 (2011). This change became effective for proceedings initiated on or after the date of the enactment of the AIA, which was September 26, 2011. *Id.*

To satisfy the best mode requirement, the patent specification must set forth the best mode contemplated by the inventor for carrying out the claimed invention. *Liquid Dynamics Corp. v. Vaughn Co., Inc.*, 449 F.3d 1209, 1223 (Fed. Cir. 2006). To establish a failure to satisfy the best mode requirement, the party challenging the patent's validity must prove by clear and convincing evidence "that the inventor both knew of and concealed a better mode of carrying out the claimed invention than that set forth in the specification." *Id.* A patent need not disclose routine details about the invention if such details would be readily apparent to a person of ordinary skill in the art. *Id.*

2. Material Facts Regarding Defenses Under 35 U.S.C. §112

Arthrex alleges that claim 24 of the '311 patent, claims 16 and 19 of the '942 patent, and each asserted claim of the '969 patent are invalid because the patent specification does not include a written description of the claimed invention, does not enable one of skill in the art to make and use the invention, and also fails to disclose the best mode contemplated by the inventors. These claims generally recite coupling suture to an anchor prior to inserting the anchor into bone. *See* '311 patent, claim 24 ("wherein suture is coupled to the second anchor prior to insertion"); '942 patent, claim 16 ("coupling the first length of suture to the second anchor prior to inserting the distal member of the second anchor"); '969 patent, claim 1 ("wherein the anchor tip comprises an aperture through which suture material is threaded prior to insertion").

KFx will demonstrate that Arthrex has failed to carry its burden of proof on any of these defenses by clear and convincing evidence. For example, KFx will present evidence, which includes the KFx patents and testimony from its expert, Dr. Ticker, and one or more of the named inventors, showing that KFx's asserted patents provide more than adequate written description for each of the asserted claims. KFx similarly will present evidence showing that the patents disclose more than sufficient information to enable a person of ordinary skill in the art to make and use the claimed invention without undue experimentation.

For example, KFx will present evidence at trial to show that the KFx patents contain more than sufficient description to enable a person of ordinary skill in the art to perform a method of attaching soft tissue to bone where suture is coupled to an anchor prior to insertion of the anchor. Additionally, KFx will present evidence to show that the KFx patents sufficiently identify and describe anchors having an anchor tip with an aperture to enable a person of ordinary skill in the art to perform the claimed method. KFx will also present evidence to show that undue experimentation by a person of ordinary skill in the art would not be required in order to practice the full scope of the inventions claimed in the KFx patents.

As for the alleged best mode defense, it is not an available defense for the KFx '942 and '969 patents because those patents were not added to this case until after the effective date of the AIA. Specifically, the '942 and '969 patents were added to this case on April 3, 2012, which is after the relevant AIA effective date of September 26, 2011.

With respect to the "best mode" for claim 24 of the '311 patent, KFx will demonstrate that Arthrex has failed to carry its burden of proof by clear and convincing evidence. Indeed, Arthrex has not identified any mode for practicing the invention of claim 24 of the '311 patent that the inventors

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considered superior to others or any mode that was not described in the patent specification.

H. Permanent Injunction

1. Points of Law Regarding Issuance of a Permanent Injunction

After a finding of patent infringement, 35 U.S.C. § 283 provides that courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." To obtain a permanent injunction:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 126 S.Ct. 1837, 1839 (2006). A patentee's right to a permanent injunction is determined after establishing infringement of a valid patent. *Id.*

2. Material Facts Regarding Issuance of a Permanent Injunction

Upon a finding of infringement, KFx will seek a permanent injunction and present any additional evidence that might be necessary to establish that:

(1) KFx has suffered an irreparable injury as a result of Arthrex's infringement of the KFx patents;

(2) remedies at law, such as monetary damages, are inadequate to compensate KFx for the injury suffered as a result of Arthrex's infringement;

(3) an injunction is warranted in view of the balance of hardships between KFx and Arthrex; and

(4) the public interest would not be disserved by permanently enjoining Arthrex from infringing KFx's patents.

I. Inequitable Conduct

1. Points of Law Regarding Inequitable Conduct

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson And Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). What remains of Arthrex's inequitable conduct defense is subject to KFx's pending motion for summary judgment. In the event it would be tried, however, the defense is appropriately tried to the Court. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed. Cir. 2000).

To prove inequitable conduct, the accused infringer must prove by clear and convincing evidence "that the applicant (1) made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [Patent and Trademark Office]." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008) (quoting *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1363 (Fed. Cir. 2007)). Because intent and materiality are separate elements, a strong showing on one element cannot compensate for an insufficient showing on the other. *Therasense*, 649 F.3d at 1290.

Materiality required for inequitable conduct is "but-for" materiality, *i.e.*, the information is so material that "but for" the information being withheld from the Patent Office the patent would not have been granted. *Id.* at 1291. As for intent to deceive the Patent Office, the evidence "must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." *Id.* at 1290 (emphasis provided by the court) (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988)). Thus, if multiple reasonable inferences may be drawn from the evidence, deceptive intent cannot be found. *Id.* at 1290-91.

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2. Material Facts Regarding Inequitable Conduct

In May 2012 KFx filed a motion to dismiss Arthrex's three inequitable conduct claims relating to the '942 and '969 patents. D.I. 30. The Court dismissed Arthrex's third ground for inequitable conduct, but found that Arthrex's first and second grounds satisfied the pleading standard. *Id.* at 5-8. In July 2012 KFx filed a motion for summary judgment regarding Arthrex's allegation of inequitable conduct in connection with the '311 patent, D.I. 39, which the Court granted on October 15, 2012, D.I. 65. KFx has since filed a motion for summary judgment regarding Arthrex's remaining two grounds for inequitable conduct in connection with the '942 and '969 patents. That motion is currently pending before the Court.

If the Court were to deny KFx's pending motion, KFx will demonstrate at trial before this Court that Arthrex has failed to prove by clear and convincing evidence that KFx failed to disclose material information with intent to deceive the Patent Office. KFx will introduce evidence at trial to show that Ryan Melnick, KFx's patent attorney, did not act with deceptive intent.

Finally, KFx will demonstrate that Mr. Melnick's alleged misconduct was not material to the issuance of the '942 or '969 patents. For example, KFx will introduce evidence at trial to show that the examiner considered the same materials that Arthrex claims Mr. Melnick diverted from the examiner's attention.

III. ABANDONED ISSUES

KFx no longer seeks a judgment of infringement vis-à-vis Arthrex's Achilles SutureBridge and SpeedBridge procedures.

IV. EXHIBITS

KFx has attached hereto a list of exhibits that it expects to offer at trial other than those to be used for impeachment.

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V. WITNESSES

KFx has attached hereto a list of witnesses that it expects to offer at trial.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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